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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Paper No. 3

Application Number: 09/425,501
Filing Date: October 22, 1999
Appellant(s): MARK ET AL.

Gavin Bogle
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed on September 8, 2003.

(1) Real Party in Interest

A statement identifying the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

A statement identifying the related appeals and interferences which will directly affect or be directly affected by or have a bearing on the decision in the pending appeal is contained in the brief.

(3) Status of Claims

The statement of the status of the claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Invention

The summary of invention contained in the brief is correct.

(6) Issues

The appellant's statement of the issues in the brief is correct.

(7) Grouping of Claims

Appellant's brief includes a statement that claims 43-65 do not stand or fall together and provides reasons as set forth in 37 CFR 1.192(c)(7) and (c)(8).

(8) Claims Appealed

The copy of the appealed claims contained in the Appendix to the brief is correct.

(9) Prior Art of Record

Nagase et al. Prediction of the coding sequences of unidentified human genes. DNA Res., Vol. 3, pages 321-329, 1996.

(10) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

A. Claim 43-65 are rejected under 35 U.S.C. 102(b) as being anticipated by Nagase et al. (DNA Res., 3: 321-329, 1996).

Nagase et al. teaches the coding sequence of cDNA clone from human myeloid cell line KG-1 and brain wherein Nagase et al. disclose a cDNA clone which is identical or absolute homology (100%) to the claimed sequences in SEQ ID Nos. 1 and 2 of the instant invention (see sequence alignment from GenEmbl. and Swissprot_39 databases). Nagase et al. also disclose that the cDNA clones showed homology to the genes that play key roles in regulation of developmental stages, apoptosis and cell-to-cell interaction (see page 321, abstract). Thus the disclosure of Nagase et al. meets the limitations in the instant claims.

Claims 49-53 and 57-59 are rejected under 35U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The current claim 49 is drawn to a genus (fragments) of Bcl-xL nucleic acid comprising a nucleic acid encoding 85% amino acid homology to SEQ ID NO: 2, claim 50 drawn to a binding domain which hybridizes to a complement of a nucleotide sequence SEQ ID NO.1 and a nucleic acid encoding Bcl-xL binding protein as shown in SEQ ID NO.1. This large genus is represented in the specification by the named SEQ ID Nos. 1 and 2. Thus, applicant has expressed possession of only one species in a genus, which comprises hundreds of millions of different possibilities. The written description guidelines note regarding such genus/species situations that "Satisfactory disclosure of a ``representative number" depends on whether one of skill in the art would recognize that the applicant was in possession of the necessary common attributes or features of the elements possessed by the members of the genus in view of the species

disclosed." (See: Federal Register: December 21, 1999 (Volume 64, Number 244), revised guidelines for written description.) Here, no common elements or attributes of the sequences are disclosed in the sequences with 85% homology. With regard to the sequences, which have 85% homology, this is insufficient to demonstrate identity of Bcl-xL binding and function where no structural information regarding where in the protein the binding and function resides. The recitation of amino acids 419-559 or 429-559 in Bcl-xL binding domain in claim 53 do not specify the exact site for binding and the activity of the protein. Further no information is given regarding a methodology to determine such common elements or attributes. Further, for hybridization purposes, even a fragment of any length which comprises partial sequence of SEQ ID NO.1 hybridizes with the SEQ ID NO. 1. It is not necessary to have a full length sequence of the said SEQ ID NO. 1 for hybridization. Thus, there is no description of fragments or complementary nucleic acid sequence that hybridize to SEQ ID NO. 1.

With regard to the written description, all of these claims encompass nucleic acid sequences different from those disclosed in the specific SEQ ID Nos: 1 and 2 which include modifications by permitted by the 85% language for which no written description is provided in the specification.

> It is noted that in Fiers v. Sugano (25 USPQ2d, 1601), the Fed. Cir. concluded that "...if inventor is unable to envision detailed chemical structure of DNA sequence coding for specific protein, as well as method of obtaining it, then conception is not achieved until reduction to practice has occurred, that is, until after gene has been isolated...conception of any chemical substance, requires definition of that substance other than by its functional utility."

In the instant application, only the amino acid sequence of the disclosed SEQ ID Nos are described. Also, in Vas-Cath Inc. v. Mahurkar (19 USPQ2d 1111, CAFC 1991), it was concluded that:

> "...applicant must also convey, with reasonable clarity to those skilled in art, that applicant, as of filing date sought, was in possession of invention, with invention being, for purposes of "written description" inquiry, whatever is presently claimed."

In the application at the time of filing, there is no record or description which would demonstrate conception or written description of any amino acids modified by addition, insertion, deletion, substitution or inversion with the disclosed SEQ ID Nos. but retaining correlative function in the claimed product.

(11) Response to Argument

Introduction

The current claims are drawn to an isolated nucleic acid comprising a nucleotide sequence encoding an isolated human Bcl-XL binding protein set forth in SEQ ID No. 1, which encodes the amino acid sequence set forth in SEQ ID No. 2. The dependent claims are further drawn to variants or fragments of the isolated human Bcl-XL binding protein having a degree of homology to SEQ ID NO. 2. The current claims are further drawn to recombinant expression vector and transformed cell lines stably expressing said Pablo polypeptide comprising said sequences set forth in SEQ ID NO.1 and 2. The said Bcl-binding protein is claimed to modulate apoptosis.

Anticipation

The anticipation is based on the prior art reference, Nagase et al. (DNA Res., Vol. 3, pages 321-329, 1996). Nagase et al. disclose a full length nucleotide sequence identical to the instant SEQ ID NO. 1 an amino acid sequence identical to the instant SEQ ID NO. 2. Further Nagase et al. disclose said full length sequence is derived from a human myeloid cell line KG-1 and brain. Nagase et al. also disclose that the cDNA clones showed homology to the genes that play key roles in regulation of developmental stages, apoptosis and cell-to-cell interaction (see page 321, abstract). Thus the disclosure of Nagase et al. anticipates the current claims.

Appellants' analysis on the rejection under 35 U.S.C 102(b) and the arguments are fully considered and found unpersuasive. On page 3 of the Appeal Brief, Appellant argues that Nagase et al. merely discloses the primary structure of a protein without an indication of a use for the invention and thus Nagase et la. Does not provide an enabling disclosure of the instant invention. Further on page 4 of the Appeal Brief, Appellant argues that Nagase et al. does not suggest that the peptide will bind to Bcl-XL or that the peptide will modulate apoptosis and thus the disclosure of Nagase et al. is not operable and is not an enabling art. These arguments are fully considered and found not persuasive.

Examiner notes that one of ordinary skill in the art would relay on the Nagase et al. reference as an enabling art for the isolated sequences as claimed in the instant invention because it is noted in MPEP 2122, in order to constitute anticipatory prior art, a reference must identically disclose the claimed compound, but no utility need be disclosed by the reference. In re Schoenwald, 964 F.2d 1122, 22 USPQ2d 1671 (Fed. Cir. 1992). Thus Nagase et al. anticipates the instant claims and the disclosure of Nagase et al. is an enabling art. The primary chemical sequence is known in the art as disclosed by Nagase et al. and thus the prior art is operable MPEP 2121.02 further states "a reference is presumed operable until applicant provides facts rebutting the presumption of operability. In re Sasse, 629 F.2d 675, 207 USPQ 107 (CCPA 1980). Therefore, applicant must provide evidence showing that a process for making was not known at the time of the invention. The citations to the utility guidelines is irrelevant because the prior art is not required to be useful to anticipate. The chemical sequence is known in the art as disclosed by Nagase et al. Thus the reference is operable under ordinary circumstances.

On page 5 of the Appeal Brief, Appellants further argue that the fragments encoding the

sequence set forth in SEQ ID Nos. 1 and 2 are not anticipated by Nagase et al. because Nagase et al. does not disclose structure of any useful fragments, which contain the specific binding sites that modulates apoptosis. These arguments are fully considered and found unpersuasive. The primary sequence is disclosed by the prior art of the record and the fragments encoding the sequence are inherent in the sequence disclosed. As MPEP 2112 states, "Products of identical chemical composition can not have mutually exclusive properties." A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. In re Spada, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). Since the sequence is known in the art, the properties are inherent and are insepaerable. One of the ordinary skill in the art could synthesize any fragment encoding the known sequence using a selection from extremely well known methods ranging from simple chemical synthesis to ligation to PCR amplification with 100% expectation of success. Thus the claimed fragments are anticipated by the disclosure of Nagase et al.

Lack of written description for the claimed fragments

The current claims are drawn to fragments comprising the sequence set forth in SEQ ID Nos. 1 and 2. The claims are drawn to hybridizable fragments, hybridizable to the complement of a nucleotide sequence set forth in SEQ ID No.1 and fragments having 91% sequence homology to the sequence set forth in SEQ ID NO. 1. These large number of hybridizable fragments and fragments having at least 91% sequence homology are not supported by the specification.

Appellants argue that the binding domain is disclosed and the length of amino acid residues is disclosed in the specification. The arguments on hybridizable fragments and the fragments

having homology (claim 65 is rejected based on its 91%homology language) are fully considered and found unpersuasive. Hybridizable fragments comprise a single base complement fragment to a maximum length of hundreds of nucleotide bases with the given binding domain. The hybridization conditions recited in the claims do not recite the actual number of fragments that can be isolated based on the hybridisable language. for hybridization purposes, even a fragment of any length, which comprises partial sequence of SEQ ID NO.1, hybridizes with the SEQ ID NO. 1. It is not necessary to have a full length sequence of the said SEQ ID NO. 1 for hybridization. Thus, there is no description of fragments or complementary nucleic acid sequence that hybridize to SEQ ID NO. 1.

Further fragments having 91% homology comprise any variation between one base to several bases substitution, deletion, addition or insertion. By permutations and combinations the hybridisable fragments and fragments having 91% homology constitute a large number of species for which the specification lacks support. The specification does not support that each and every fragment complementary to SEQ ID No.1 would modulate apoptosis. Thus the rejection under 35 U.S.C. 112, first paragraph should be sustained.

Conclusion

For the reasons above the full length and the fragments as claimed in the instant invention are anticipated and lack support in the specification for the large number of fragments encoding the claimed SEQ ID Nos. 1 and 2. Thus the rejections under 35 U.S.C. 102(b) and 35 U.S.C. 112, first paragraph should be sustained.

Respectfully submitted,

Suryaprabha Chunduru
Examiner
Art Unit 1637

June 2, 2004

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